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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,432	10/15/2001	Chen-Kun James Shen	08919-016003	3256

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/977,432	SHEN, CHEN-KUN JAMES	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *33-40,45,46 and 51-57*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER
1/26/05

[1]Continuation of 5. does NOT place the application in condition for allowance because:

Claims 33-36, 45-46 and 51-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (JBC 270(15):8501-8505, 1995, ref of record) in view of Miller et al (Biotechniques 7(9):980-990, 1989 ref of record), for the same reasons of record as set forth in the office action mailed on 12/03/04.
In addition, claims 37-40 and 54-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (JBC 270(15):8501-8505, 1995, ref of record) in view of Miller et al (Biotechniques 7(9):980-990, 1989 ref of record) as applied to claims 33-36, 41-46 and 51-53 above, and further in view of Jarman et al (Mol. Cell. Bio. 11(9):4679-4689, 1991; ref of record), for the same reasons of record as set forth in the office action mailed on 12/03/04

Response to arguments
The applicant argues that the retroviral vector comprising ζ-globin enhacner (as claimed) is an unexpected result and as a result one skilled in the art would not have been motivated to make retroviral vectors containing the ζ-globin enhancer region. The applicant argues that in view of MPEP 716.02(a) and as well as In re Chupp, 816 F2nd 643, 646, 2USPQ2nd 1437, 1439 (Fed Cir. 1987) the unexpected high-level expression in transgenic animals is enough to rebut prima facie case of obviousness. The applicant argues that as in In re Chupp, evidence showing that the claimed (expression vector) was more effective than the closest prior art (vector for expression in an animal) was sufficient to overcome the rejection under 35 U.S.C. 103, even though the claimed (vector) was an average performer (for expression in a cell line).

However, this is found NOT persuasive because the invention as claimed is drawn to a retroviral vector encoding a ζ -globin enhancer operatively linked to promoter that drives the expression of a gene of interest. As stated in the earlier office action Lung et al (ref cited by applicant) clearly teaches that a retroviral vector containing an HS-40 enhancer provides high level of in MEL cells (see abstract, page 614, fig-1). In addition the declaration by Dr. Shen only teaches transgene expression (mtHS40-zGH) in transgenic mice which does not support applicants assertion that a retroviral vector as claimed is an unexpected finding, especially in view of fact that a retroviral vector containing an HS-40 enhancer is capable of providing a high level of gene expression in isolated MEL cells (see Lung et al). Furthermore any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case as demonstrated by Lung et al (ref cited by applicant) a retroviral vector containing an HS-40 enhancer is capable of providing high level of gene expression in MEL cells (see abstract, page 614, fig-1). Thus the invention as claimed is not an unexpected result but a prima facie obvious product in view of cited prior art of record